

(12) UK Patent Application (19) GB (11) 2 118 045 A

(21) Application No 8300499

(22) Date of filing 10 Jan 1983

(30) Priority data

(31) 3414201

(32) 13 Apr 1982

(33) Soviet Union (SU)

(43) Application published

26 Oct 1983

(51) INT CL³

A61F 9/00 A61B 17/00

(52) Domestic classification

A5R EK

(56) Documents cited

GB 1591637

GB 1515236

GB 1215881

EP A1 0005719

US 3882872

(58) Field of search

A5R

(71) Applicant

Gorkovsky

Gosudarstvenny

Meditsinsky Institut Imeni

S. M. Kirova

(USSR),

ploshad Minina i

Posharskogo, 1/10 Gorky,

Union of Soviet Socialist

Republics

(72) Inventors

Leopold Vladislavovich

Kossovsky,

Jury Klementievich

Kravchuk,

Alexandr Vasilievich

Boiko,

Zinovy Mikhailovich

Slavinsky,

Georgy Evgenievich

Stolyarenko,

Irina Leopoldovna

Kossovskaya,

Alexandr Ivanovich

Sorokin

(74) Agent and/or Address for
Service

Marks and Clerk,

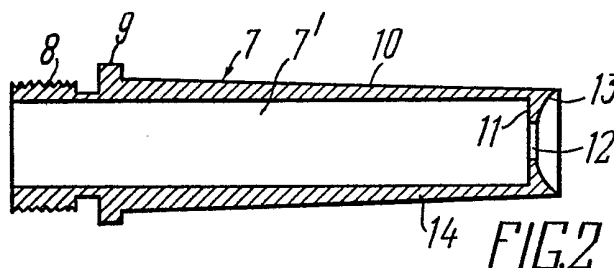
57—60 Lincoln's Inn

Fields, London WC2A 3LS

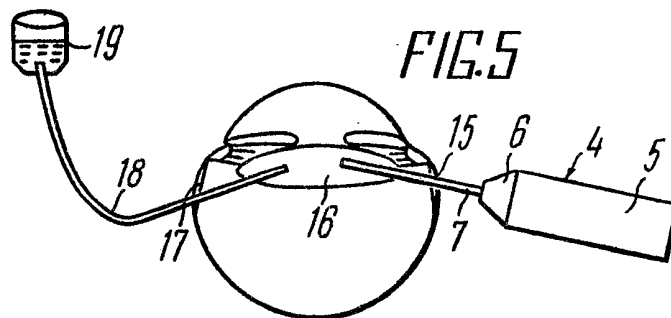
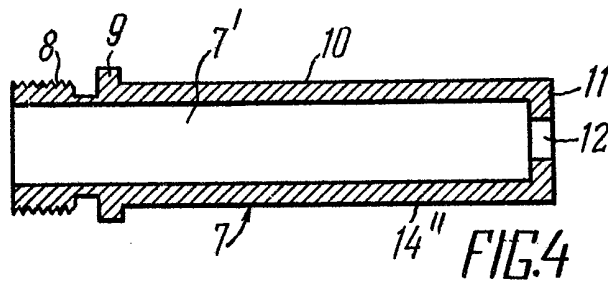
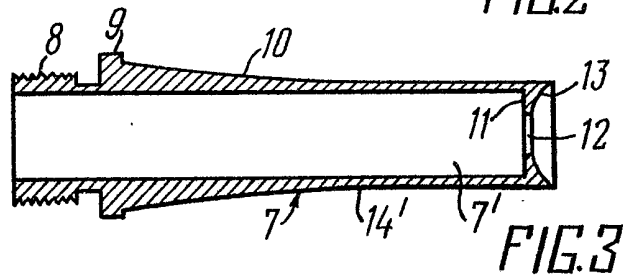
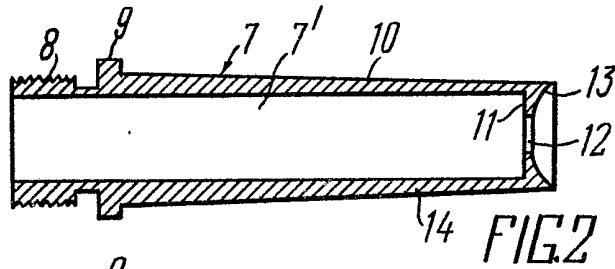
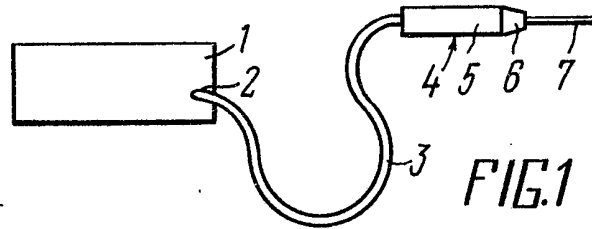
(54) **Apparatus for the
fragmentation and aspiration of
ocular tissues**

(57) An apparatus for the
fragmentation and aspiration of ocular
tissues comprises a controlled
ultrasonic generator connected to a
magnetostriction converter to produce
mechanical ultrasonic vibrations
transmitted therefrom to a hollow

needle (7) joined thereto. The end of
the needle remote from its other end
connected to the magnetostriction
converter is adapted to be brought
into contact with the ocular tissue
under fragmentation and has an end
wall portion (11) with a through
opening (12) having a diameter of
substantially between 1/3 and 2/3 of
the diameter of the needle bore (7').
The outer surface (14) of the needle
can be shaped as a cone or a cylinder.



GB 2 118 045 A



SPECIFICATION

Apparatus for the fragmentation and aspiration of ocular tissues

This invention relates to apparatus for the
 5 fragmentation and aspiration of ocular tissues, relying on the use of ultrasound. The apparatus of the invention will be found most useful in operative procedures involving the removal of cataracts, as well as the vitreous, blood clots,
 10 fibrin membranes, and exudates.

At the present time a highly promising technique of cataract extraction consists in fragmenting the opacified lens directly *in situ* combined with the simultaneous suction of the
 15 fragmented mass. This technique is far less traumatic compared to the conventional methods of cataract removal, for example cryophakia, since it requires an operative incision of but a small size to permit the introduction of a needle or an
 20 instrument tip into the eye. A similar situation occurs in respect of excision of the pathologically affected vitreous, as well as in pathological changes involving other tissues (fibrin membranes, blood clots, exudates).

An embodiment of the method relies on the use of mechanical devices, vitreotomes, for example such as that described in US Patent No. 3 882 872. The instrument referred to consists of a mechanical drive, aspiration unit, and a working tip
 30 shaped as two coaxially arranged tubes interacting by their cutting edges. The tissue to be removed is sucked into the passage between the tubes and is then subjected to a shearing type cutting action while the inner tube moves.

However, such mechanical devices require continuously razor-sharp cutting edges, thereby restricting everyday use of the vitreotome. In this connection, ultrasound instruments such as phacoemulsifiers or fragmentors find an
 40 increasingly wide application.

U.S. Patent No. 3 693 613 describes an apparatus for the removal of material and a method of applying high frequency vibrations. The apparatus comprises an ultrasonic generator,
 45 magnetostriction converter, a suction means for the removal of broken tissue, and a hollow needle having a through longitudinal bore. The needle is connected to the magnetostriction converter wherefrom it receives longitudinal periodic
 50 vibrations with a frequency of about 40 Hz and an amplitude of about 30 μm . The free end portion of the needle when advanced contiguous to the lens breaks the nucleus to dust-like particles.

Simultaneously, another route is used to introduce
 55 normal saline into the eyeball to dilute the broken mass and perform its aspiration *via* the through longitudinal bore of the needle using the suction unit provided with a pump and a motor.

A serious disadvantage of this apparatus is the
 60 need to forcibly aspirate the broken mass by employing a special means provided with a pump. Continuous operation of the pump required throughout the surgery poses the danger of abrupt pressure fluctuations within the suction system if

the needle becomes blocked by large fragments broken off the lens. Such blockage of the suction channel produces surplus vacuum. Sudden dislodgement of obstruction due to changed frequency of the ultrasonic generator results in too
 70 much intraocular matter being sucked into the vacuum area since inertia of the feeding system delays restoration of the intraocular fluid balance. This may lead to such a grave complication as ocular collapse.

The additional presence of an electric motor significantly complicates the device, reducing its reliability due to the large number of moving parts and electric contacts.

Moreover, the use of such an apparatus is
 80 restricted to the removal of the lens mass, while the vitreous and other pathologically affected tissues remain inaccessible.

Another ultrasonic device for performing surgery and therapeutic treatment using ultrasonic energy is described in U.S. Patent No. 3 990 452. The essential design of this device is similar to that mentioned above with all the inherent disadvantages thereof. However, it is distinguished from the previously described
 85 apparatus by a changed shape of the needle having a tapering neck such that its apex develops into an elongate cylindrical portion terminating in an obliquely cut end. A needle of this type allows fragmentation and aspiration of the lens mass, but
 90 its application can be extended to the vitreous and a variety of pathological tissues, for example fibrin membranes and exudates. However, such a needle is designed for a single surgical operation due to rapid wear at the juncture of the conical and
 100 cylindrical portions.

The present invention provides apparatus for the fragmentation and aspiration of ocular tissues, comprising an ultrasonic generator having its outlet connected to a magnetostriction converter
 105 for converting electrical vibrations into mechanical vibrations, and a hollow needle with an axially disposed bore, having one end thereof connected to the magnetostriction converter to receive the mechanical vibrations for causing ocular tissues to
 110 be fragmented and severed tissue to be aspirated, the free other end of the said needle being adapted to be brought into contact with the tissue to be removed, the said free end of the needle being provided with an end wall portion having a
 115 through opening communicating with the said axial bore of the needle, and the diameter of the said through opening being substantially less than the diameter of the said bore.

The apparatus according to the invention dispenses with the forcible suction of broken ocular tissues, thereby substantially increasing operative safety and reliability of the apparatus.

Use of the apparatus according to the invention results in spontaneous aspiration of broken and emulsified ocular tissues. While not wishing to be bound by theory, the inventors believe that such an unexpected effect arises as a result of a very low pressure which develops at the point of direct contact between the opening in the end wall

portion and the axial bore of the needle on the one hand, and the broken tissue on the other.

The diameter of the opening in the end wall portion is preferably from about 1/3 to about 2/3 of the diameter of the axial bore of the needle, since at this quantitative relation aspiration of the emulsified mass is most effective.

Further increase of suction and fragmentation efficiency with respect to ocular tissues may be obtained by the use of a tapered needle the outer surface of which is bevelled from the end of the needle adjacent the converter of ultrasonic vibrations to the end wall portion.

Enhanced efficiency of fragmentation and aspiration of intraocular tissues is apparently due to the fact that the tapering of the needle effectively serves as an extension of a concentrator which may be suitably inserted between the magnetostriction converter and the needle, which is conducive to better transmission of longitudinal ultrasonic vibrations from the converter to the needle and, therefore, to its remote end, whereby the power of its vibrations is amplified.

Fragmenting efficiency may be further improved by the provision of a sharp cutting edge at the projecting end of the end wall portion, which sharp cutting edge more preferably extends continuously along the periphery of the end wall portion.

The sharp cutting edge of the end wall portion, in addition to the fragmenting action on intraocular tissues of a purely mechanical nature, has the properties of an ultrasound focusing element at the same time augmenting the effect of cavitation viewed as a material constituent within the mechanism of ultrasonic fragmentation.

The invention will be further described, by way of example only, with reference to the accompanying drawings, wherein:

Figure 1 is a schematic view of an apparatus according to the invention for the fragmentation and aspiration of cataracts;

Figure 2 is a cross-sectional view showing the needle of the apparatus having a bevelled outer surface and a sharp cutting edge on the end wall portion;

Figure 3 is a cross-sectional view of a needle similar to that shown in Figure 2, but provided with a parabolically shaped outer surface;

Figure 4 is a cross-sectional view of a needle having a cylindrical shape; and

Figure 5 is a schematic view showing the arrangement of the parts of the apparatus in their operative position.

Referring to Figure 1, there is shown an apparatus for the fragmentation and aspiration of cataracts, which includes a controlled ultrasonic generator 1, which is essentially any ultrasonic generator capable of providing an output frequency of vibrations of from 20 to 70 Hz, for example as disclosed in U.S. Patent No.

3 589 363. An output 2 of the generator is connected by a cable 3 to a surgical handpiece 4, which directly performs the fragmentation and

aspiration. The handpiece 4 comprises a magnetostriction converter 5 similar to the devices disclosed in U.S. Patent Nos. 3 589 363 and 3 990 452. Furthermore, this unit comprises a concentrator of ultrasonic vibrations 6, also of the type referred to in the above-mentioned U.S. patents.

A needle 7 (Figure 2) is provided with a threaded shank 8 to permit its connection to the concentrator 6, and a flat 9 for tightening of this connection with a wrench. A housing 10 of the needle 7 is made hollow and has an axial bore 7' therein. The housing 10 is provided with an end wall portion 11 arranged substantially at right angles to the axis of the bore 7'. An axial opening 12 is made through the wall 11 to communicate with the bore 7'. It has been found that the diameter of the opening 12 should preferably be in the range of from 1/3 to 2/3 of the diameter of the bore 7'. An outer edge 13 of the end wall portion is made sharp. The outer surface 14 of the housing 10 is provided with a conical bevel extending from the junction of the needle with the converter 5, thereby permitting higher concentration of the ultrasonic vibrations.

The apparatus described above is operated as follows. The needle 7 is introduced into the eye through an incision 15 in its wall, then advanced to the area of intraocular tissue to be broken apart and removed, such as lens 16. On activation of the ultrasonic generator, the electrical oscillations are transformed into mechanical vibrations in the converter 5, which are subsequently transmitted to the needle 7. The ultrasonic vibrations emitted by the needle 7 cause the tissue of the lens 16 adjacent the free end of the needle to be broken apart. The fragmented mass of intraocular tissue is sucked up due to a negative or lowered pressure produced during vibrations of the needle having the end wall portion 11 provided with the opening 12. Following fragmentation and aspiration of the intraocular tissue subject to surgical removal, the needle is withdrawn from the eye and the incision in its wall closed. Scarcity of intraocular matter by volume resulting from surgery is offset by infusion of a saline solution or a substituting fluid through a separate incision 17 made in the wall of the eye either simultaneously with aspiration or on completion of removal using a special instrument 18 from a reservoir 19.

The apparatus of this invention was surgically tested on 278 patients, 155 of which were operated for cataracts, while the remaining 123 were operated for pathology of the vitreous.

Among the cataract patients, 104 individuals presented presenile and complicated cataracts, the age range being 35 to 55 years, density of the nucleus was plus 2 and plus 3. In 31 patients a post-traumatic cataract was removed within a period of from 10 hours to 14 days following injury against a background of traumatic iridocyclitis. 20 children suffering from congenital cataracts aged 2—3 months also underwent surgery.

Among the patients with pathology of the

vitreous, 49 showed opacification of the vitreous of a post-traumatic etiology, 46 exhibited aphakic vitreous block, 23 exhibited opacification of the vitreous of a diabetic and inflammatory genesis, 5 and 5 patients exhibited endophthalmitis.

All patients showed a good anatomical response, and the functional improvement was evaluated in each case by the condition of the cornea, retina, and optical nerve.

- 10 There is described below a series of specific examples of treatment using the apparatus of this invention.

Female patient N., 52 years old, on admission diagnosed complicated cataract in the right eye.

- 15 The eye was quiet, the cornea and the anterior chamber fluid were transparent. Contours of the iris were well defined, the pupil round, 4 mm in diameter, with a vivid reaction to light. Angle of the anterior chamber was open, of moderate width, and faint pigmentation was present in the area of Schlemm's canal and corneoscleral trabeculae.

- 20 Opacity of the lens engulfed the entire mass of the lenticular matter. Visual acuity in the operated eye was 0.03. Visual field was in norm.

The intraocular pressure as registered by daily tonometry varied between 17.0 and 24.0 mm Hg.

The vitreous showed no pathological changes.

- 25 The patient underwent ultrasonic phacofragmentation surgery under local anesthesia performed through pars plana of the ciliary body using the apparatus of this invention. The instrument was operated at a frequency of 66 Hz for 2 minutes. A balanced salt solution was utilized as the substitutive fluid. Surgery was uneventful with individually performed removal of the broken lenticular matter.

- 30 In the first 1—2 day period following surgery there was mild hyperemia and swelling of the conjunctiva of the eyeball around the operative incisions. The pupillary space was free from the cortical mass.

- 35 The patient received instillations of mydriatics, hydrocortisone, and sodium sulphacyle. On the third day after surgery, in view of the abatement of inflammatory signs, the patient was discharged from hospital. Visual acuity with aphakic correction at discharge was —1.0. At the time of a follow-up examination carried out 3 months following the operated eye was quiet, the cornea was clear and had a glossy appearance. The anterior chamber was deep and filled with clear fluid. The iris was quiet with well-defined borders giving evidence of marked iridodesis. The pupil retained a round shape and vivid reaction to light, having a diameter of 3 mm. Angle of the anterior chamber was open and very wide with some build-up of the exogenous pigmentation in the area of Schlemm's canal and the corneoscleral trabecula as compared to its preoperative appearance. The central part of the pupil was clear; however, shreds of the capsular material were noted on dilating the pupil along the periphery. Fundal reflex was clear-cut; no pathological changes of the fundus were detected

ophthalmoscopically.

Visual acuity with spheric correction was —1.0. The patient exhibited a normal visual field. The intraocular pressure as provided by the daily tonometric readings varied in the range of 16.0 to 23.0 mm Hg. Echographically, there were no detectable pathological changes either in the vitreous or in the retina.

- 70 *Patient B.*, 20 years old, prior to admission documented post-traumatic cataract, opacification of the vitreous in the left eye.

Duration of cataract history documented in the patient's record was 3 years. Visual acuity in the left eye was 0.01. On examination of the visual field no pathological changes were detected.

- 80 Biomicroscopically there was some evidence of stromal atrophy affecting the iris and pupillary border. There was formation of posterior synechiae, and pigmental deposits on the anterior capsule of the lens.

Lenticular transparency partially persisted in the periphery. Gonioscopic evaluation revealed a medium width of the angle of the anterior chamber. Pigmentation of the angular zones was for the most part moderate with cone-like goniosynechiae. Echographic examination exposed destructive changes of the vitreous. The intraocular pressure as given by daily tonometry was between 22.0 and 26.0 mm Hg.

- 95 The patient underwent surgical removal of the cataract and opacity of the vitreous using the apparatus of this invention as hereinabove described.

- 100 The cataract was removed through a scleral incision 1.5 mm long made 4 mm away from the limbus in the pars plana of the ciliary body at 2 o'clock.

- 105 Another perforating incision of the sclera also 4 mm away from the libus at 10 o'clock provided an entrance through which along the equator of the lens a needle introducing a balanced salt solution was inserted. Mydriasis of the pupil was accomplished by introducing into the posterior chamber through the scleral incision a 1% mesatone solution. Operation of the instrument continued for 1.5 minutes.

- 110 Aspiration of the broken lenticular and vitreous masses was performed independently without a special suction device. The emulsion suction rate was controlled by changing the power of the transmitted ultrasonic signal. Post-operative period was uneventful.

- 115 During the first days following surgery there was a mild swelling and hyperemia of the conjunctiva, and mild evidence of iritis.

- 120 By the end of the seventh day the inflammation appeared to have resolved and the patient was discharged from hospital. At discharge the cornea and fluid in the anterior chamber was clear, and the anterior chamber was deep with the pupil retaining the round shape.

Visual acuity with correction showed by the patient at discharge was 0.8.

- 125 At the time of repeated examination the eyeball was quite, the cornea clear, and fluid in the

anterior chamber transparent. The structure of the anterior chamber was deep, even with signs of iridodonesis.

The pupil remained round in form. The pupillary area was clear.

Gonioscopically the angle of the anterior chamber was shown to be open. Exogenous pigmentation of the angular zones was moderately developed.

There were no ophthalmoscope confirmed pathological changes in the fundus. The intraocular pressure determined by daily tomography fell in the range of 16.0 to 21.0 mm Hg.

Visual acuity with correction was plus 10.0 D. was 1.0.

The needles shown in Figures 3 and 4 are substantially similar to that shown in Figure 2, the only difference being that the surface 14 of the needle shown in Figure 3 is made parabolic, while the surface 14 of the needle shown in Figure 4 is made cylindrical and has no sharp edge corresponding to the edge 13.

CLAIMS

1. Apparatus for the fragmentation and aspiration of ocular tissues, comprising an ultrasonic generator having its outlet connected to a magnetostriction converter for converting electrical vibrations into mechanical vibrations, and a hollow needle with an axially disposed bore,

having one end thereof connected to the magnetostriction converter to receive the mechanical vibrations for causing ocular tissues to be fragmented and severed tissue to be aspirated, the free other end of the said needle being adapted to be brought into contact with the tissue to be removed, the said free end of the needle being provided with an end wall portion having a through opening communicating with the said axial bore of the needle, and the diameter of the said through opening being substantially less than the diameter of the said bore.

2. Apparatus as claimed in Claim 1, wherein the diameter of the said opening of the end wall portion is from $1/3$ to $2/3$ of the diameter of the said needle bore.

3. Apparatus as claimed in Claim 1 or 2, wherein the outer surface of the needle is bevelled from the end of the needle adjacent the converter of ultrasonic vibrations to the said end wall portion.

4. Apparatus as claimed in any of Claims 1 to 3, wherein a projecting end of the said end wall portion has a sharp cutting edge.

5. Apparatus as claimed in Claim 4, wherein the said sharp cutting edge extends continuously over the periphery of the said end wall portion.

6. Apparatus according to Claim 1 for the fragmentation and aspiration of ocular tissues, substantially as herein described with reference to, and as shown in, Figure 1 and Figure 2, 3 or 4 of the accompanying drawings.